THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 34

UNITED STATES BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JAMES C. HUDSON, THOMAS RUSSELL,
CARLOS M. RODRIGUEZ, and WALLACE H. COULTER

Appeal No. 95-2889[1]
Application No. 07/525,231

ON BRIEF[2]

Before GARRIS, FLEMING, and TORCZON, Administrative Patent Judges.

TORCZON, Administrative Patent Judge.

DECISION ON APPEAL

Appellants seek review under 35 U.S.C. § 134 of the final rejection of claims 1-32 (Paper No. 9 (Not. App.)). We affirm in part and enter a new ground of rejection.

BACKGROUND

Appellants filed the subject application for patent on 17 May 1990 (Paper No. 1 (appl. for CIP) at 1). They claim benefit under 35 U.S.C. § 120 of application no. 07/339,156 filed 14 April 1989, now abandoned; application no.

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[1] Attorney docket no.32267.

[2] Counsel waived the scheduled oral hearing (Paper No. 33).

07/285,856, filed 16 December 1988, now abandoned; and application no. 07/025,345, filed 13 March 1987, now abandoned (Paper No. 1 at 1).

The claimed subject matter is directed to an electronic method and apparatus for obtaining a cell population analysis of a group of cells of interest (e.g., T-cells) within a sample when the cells of interest are normally not specifically detectable within the class of cells to which they belong (e.g., lymphocytes). In the claimed invention cells of the class containing the cells of interest are counted first. The cells of interest are then labeled with microspheres, changing a property of the cells of interest such that these cells are shifted into a distinct class of cells and are no longer electronically sensed as being part of the class in which they originally belong. The remaining cells from the class in which the cells of interest belong are again counted to obtain a second count. A comparison of the first and second counts is used to obtain the number of the cells of interest present in the blood sample (Paper No. 1 at 12 and 13).

The examiner rejected claims 10, 16, 26 and 32 under

35 U.S.C. § 112[2] as failing to particularly point out and distinctly claim the subject matter that Appellants regard as their invention (Paper No. 17 (Ex. Ans.) at 3).

The examiner rejected claims 1-6, 9-13, 15-22, 25-29, 31, and 32 under 35 U.S.C. § 103 as having been obvious in view of the following references (Paper No. 17 at 3):

Suzuki	4,747,685	31 May 1988
Saunders et al. (Saunders)	4,599,307	8 July 1986

Claims 7-8, 23, and 24 were rejected under 35 U.S.C. § 103 as having been obvious over Suzuki, Saunders, and the following reference (Paper No. 17 at 4):

Rose et al. (Rose)	4,677,061	30 June 1987

The examiner rejected claims 14 and 30 as having been obvious over Suzuki, Saunders, and the following reference (Paper No. 17 at 5):

Schwartz	4,828,984	9 May 1989

DISCUSSION

Appellants request independent consideration of three groups of claims (Paper No. 13 (App. Br.) at 7-9, 22, and 23)[3]:

Group I: claims 1-9 and 17-25;

Group II: claims 10-13, 16, 26-28, 29, and 32; and

Group III: claims 14, 15, 30, and 31

The claims

Claim 1, which is representative of the claimed subject matter, is reproduced below:

> 1. A method of obtaining at least one obscured or partially obscured population analysis from at least a portion of a sample having at least a first cell population including at least one population subset of interest and a second cell population, comprising:
> electronically sensing and counting a first population including at least the first cell population and subsets thereof to form a first count;
> shifting the cell population subset of interest out of said first cell population and at least partially into a second cell population by binding microspheres having a reactant bonded thereto specific to said cell population subset of interest to said cell population subset;
> electronically sensing and counting the remaining first population including at least the

[3] While Appellants separate the claims into ten groups, they state that groups 1, 2, 6, and 7 stand or fall together, that groups 3, 4, 8, and 9 stand or fall together, and that groups 5 and 10 stand or fall together (Paper No. 13 at 22-23).

> first cell population without the shifted subset and with remaining subsets thereof to form a second count; and
>
> comparing said first and second counts to obtain the percentage contribution of the cell population subset of interest.

In claim 10, Appellants further require the microspheres of claim 1 to be "substantially smaller" than the cells of the population subset of interest wherein these cells are white blood cells of interest.

Independent claim 17 is directed to an apparatus with means corresponding to the steps of claim 1.

35 U.S.C. § 112[2]

The examiner rejected claims 10, 16, 26 and 32, arguing that the phrase "substantially smaller", as it appears in these claims, does not "clearly define the metes and bounds of the invention." (Paper No. 17 at 3). Examples in the specification of the microsphere size range from 0.7 to 3 microns (Paper No. 1 at 44, 48, and 49).

The Appellants have the burden of defining the invention precisely. In re Morris, 127 F.3d 1048, 1056, 44 USPQ2d 1023, 1029 (Fed. Cir. 1997). When a word of degree such as "substantially" is used within a claim, in order to meet their burden, Appellants must provide some standard for measuring that degree within their specification. Seattle Box Co. v.

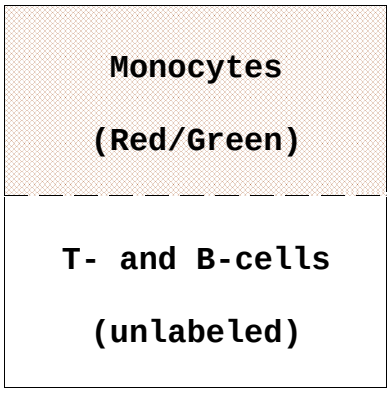
Industrial Crating & Packing, 731 F.2d 818, 826, 221 USPQ 568, 573-74 (Fed. Cir. 1984). Appellants have not directed us to any such standard. Appellants' specification does not contain the phrase "substantially smaller" so we cannot look to the specification for a specific definition of the term "substantially". While the specification provides examples where the microspheres are smaller than the white blood cells of interest, approximately one-twelfth to one-third the size of these cells, nothing in the specification limits the claimed range "substantially smaller" to the size range covered by these examples. Without a specific definition or other link between the claims and the examples within the specification, one skilled in the art could not ascertain the upper limit of particle sizes that meet the limitation of being "substantially smaller" than the white blood cells of interest short of the actual size of the white blood cells. For example, is a particle which is nine-tenths the size of a white blood cell of interest "substantially smaller" than the white blood cell? Neither the disclosure nor the claims provide the answer. On this record, Appellants have not met their burden of precisely defining the invention, so we affirm the examiner's rejection under 35 U.S.C. § 112[2].

35 U.S.C. § 103 over Suzuki and Saunders

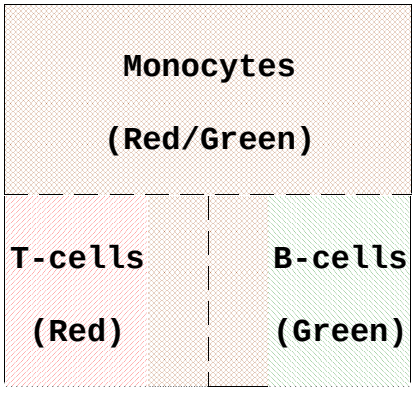
Suzuki is directed to a method and apparatus for electronically counting T-cells within a sample. T-cells are bound to antibody-coated microspheres to form complexes of a size that the apparatus can separately detect and thus selectively count (Suzuki at 1:60 to 2:16). The examiner acknowledged that Suzuki does not teach a step of comparing the white blood cell count before the microspheres are bound to T-cells with a count of the cells remaining after the T-cells are bound (Paper No. 17 at 3).

Saunders teaches a method of cell counting in which the effect of certain mononuclear cells (e.g., monocytes) that normally interfere with the counting of other mononuclear cells is removed. In one embodiment, a count of T- and B-cells (i.e., lymphocytes) within a sample is obtained through the following steps:

1) To obtain a first count, monocytes within the sample are bound to antibodies labeled with both red and green fluorochromes such that the labeled monocytes may be counted by fluorescence detectors. A schematic illustration of the sample as it is labeled for the first count appears below:



2) To obtain a second count, monocytes are again bound to the same red and green labeled antibodies as in step 1. In addition, T-cells are bound to antibodies labeled with the red fluorochrome and B-cells are bound to antibodies labeled with the green fluorochrome. Some of the lymphocytes bind to both T- and B-cell antibodies and thus will be detected as monocytes. A schematic illustration of the sample as it is labeled for the second count appears below:



3) The number of lymphocytes labeled with both T- and

B-cell antibodies is determined by subtracting the cells labeled both red and green in the first count (i.e., the monocytes alone) from the cells labeled both red and green in the second count (i.e., the monocytes plus the lymphocytes labeled with both T-cell and B-cell antibody). The difference is added to the total number of lymphocytes detected to provide a more accurate count of the total percentage of T- and B-cells present (Saunders at 8:65-9:28).

The examiner finds that Saunders' step of subtracting the first monocyte count from the second monocyte count (step 3, above) suggests the presently claimed step of comparing first and second counts (Paper No. 17 at 7).

"In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." In re Lintner, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972). The question is not whether the modification could be made, but rather "whether it was obvious to do so in light of all

the relevant factors." Arkie Lures, Inc. v. Gene Larew Tackle, Inc., 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997).

One skilled in the art may have been able to modify Suzuki by comparing counts of the population of cells before and after T-cell removal to arrive at a T-cell count; however, we find nothing in Suzuki, Saunders, or the examiner's arguments that persuades us that one skilled in the art would have been motivated to modify from the direct counting method of Suzuki and to select an indirect method of counting as presently claimed. Suzuki does not suggest that anything other than a direct count of the labeled T-cells is desirable. Saunders, while teaching an indirect count to obtain a more accurate T- and B-cell count, is directed to a different method of labeling and detection. One skilled in the art would not have looked to Saunders for guidance when counting a cell population of interest using the Suzuki method or vice versa. Combining references without evidence of a suggestion, teaching, or motivation is the essence of hindsight. In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). Consequently, we reverse the rejection of independent claims 1 and 17. The rejection of dependent claims 1-6, 9-23, 15, 16, 18-22, 25-29, 31, and 32 is also reversed.

We find nothing in Rose or Schwartz to overcome the deficience in the teachings of Suzuki and Saunders so we reverse the § 103 rejections of the remaining dependent claims as well.

New Ground of Rejection under 37 CFR § 1.196(b)

Claims 11, 12, 27 and 28 were not rejected under 35 U.S.C. § 112[2] even though they depend from claims 10, 16, 26, and 32, which were rejected under § 112[2]. Since we have affirmed the rejection of claims 10, 16, 26, and 32 under § 112[2], we now extend that rejection to include claims 11, 12, 27 and 28.

DECISION

We affirm the examiner's rejection of claims 10, 16, 26 and 32 under 35 U.S.C. § 112[2] and set forth a new ground of rejection under § 112[2] as to claims 11, 12, 27 and 28. We reverse the examiner’s rejection of all the claims under 35 U.S.C. § 103.

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b). Appellants must pursue one of the options under section 1.196(b) WITHIN TWO MONTHS FROM THE DATE

OF THE DECISION to avoid termination within the meaning of 37 CFR § 1.197(c). A decision with a new ground of rejection is not a final agency action for the purposes of seeking judicial review. If further prosecution before the examiner does not result in allowance of the application, abandonment, or a second appeal, this case should be returned to the Board for final action on the affirmed rejection, including any timely request for rehearing.

No time for taking any subsequent action in connection with this appeal may be extended under 37 CFR. § 1.136(a).

AFFIRMED-IN-PART; 37 CFR § 1.196(b)

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